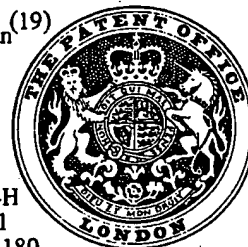


**1 576 418**

- (21) Application No. 5337/76 (22) Filed 21 Dec 1976  
(31) Convention Application No. 643405 (32) Filed 22 Dec 1975 in (19)  
(33) United States of America (US)  
(44) Complete Specification Published 8 Oct 1980  
(51) INT. CL.<sup>3</sup> B29D 27/00  
A61C 13/08  
(52) Index at Acceptance B5A 1R214A 1R214B 1R214F 1R214H  
1R314C1F 1R454A 1R454B 20N1  
20N7 20T3 A2 C3C 128 150 180  
182 184 375 C3Y B120 B122 B123



**(54) ENDOSSEOUS PLASTICS IMPLANT AND METHOD OF IMPLANT MANUFACTURE**

(71) I, ARTHUR ASHMAN, a citizen of the United States of America, of 200 Central Park South, New York, State of New York, United States of America, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

The present invention relates to prosthesis materials for artificial bones or teeth and particularly to a plastics implant and a method for fabricating such a plastics implant which can if desired produce a controlled surface porosity, with pore size depending upon the nature of tissue ingrowth desired.

In the related fields of dental implantology and orthopedic and surgical repair and replacement, numerous implant materials have been used with varying degrees of success. 20 Metallic implants and prostheses, for example, have been found to have drawbacks due to chemical and electrolytic reactions, body rejection toxic response, metal fatigue and failure, interference with healing, and inability 25 to bond with bone. More recently, ceramics and polymers have been used with improved results insofar as bodily reaction is concerned, but problems still remain in developing permanent fibrous connective tissue and/or bony 30 attachment (fixation) at the implant site.

Providing an implant with a porous surface at its interface with bone or other tissue has been recognized as promoting a firm union between the implant and the adjacent membrane in which it is embedded. For example, U.S. Patent No. 3,628,248 issued December 21, 1971 to E. A. Kroder et al. describes a procedure for preparing a tooth root replica implant from a mixture of polymethyl meth-

acrylate beads and potassium chloride granules 40  
in a weight ratio of approximately 4:1. The  
powder mixture is combined with liquid  
monomer and a small amount of benzoyl  
peroxide (to initiate polymerization) in a mold  
for self-curing. After removal from the mold, 45  
the root implant is placed in boiling water for  
about 1 minute to extract a portion of the  
potassium chloride, thereby producing poro-  
sity.

As pointed out, however, in U.S. Patent No. 50 3,713,860, issued January 30, 1973 to A. Auskern, residues of additives to methyl methacrylate monomer, such as inhibitor, catalyst, or promoter, may cause tissue reactions at the implant site, and the benzoyl 55 peroxide initiator of Kroder is known to be toxic to human tissues. The Auskern patent discloses a porous ceramic aluminium oxide bone substitute that is impregnated with pure methyl methacrylate (MMA) monomer. The 60 monomer is then polymerized by gamma radiation from a suitable source, such as cobalt-60. If not previously shaped to size, the plastic-reinforced ceramic body is then machined, and the areas where bone or tissue 65 ingrowth is desired are exposed to a suitable solvent (e.g. acetone) in an ultrasonic bath for 15 to 30 minutes to dissolve the polymer plastic to a preferred depth in the range of 100 to 400 microns. 70

According to Auskern, connective and bone tissue will grow into the pores and be firmly bonded to the ceramic if the porosity of the ceramic is in the range 30-50 percent by volume, with the greater number of pores being in the range of 75 to 150 microns in diameter. On the other hand, a paper published by the present applicant in The New York Journal of

Dentistry, Vol. 42, No. 10, pp. 331-341, December, 1972, suggested that the optimum porosity size for attachment between the periosteum and a polymer plastic tooth implant might fall in the range of 150-450 microns.

Another investigator has suggested a prosthesis material useful for artificial bones or teeth in the form of a heat-consolidated body composed of an integrated mixture of discrete microcrystals of calcium phosphate and a refractory compound such as aluminum oxide (see U.S. Patent No. 3,787,900 issued January 29, 1974 to T.D. McGee). In using this material for dental implants, McGee suggests providing porosity for the base of the teeth, where they fit in the alveolar sockets, by adding a volatile material such as naphthalene crystals to the dry ingredients at the root end of the implant molding before pressing and firing. In one example, forty percent naphthalene crystals were incorporated into one half of a cylindrical specimen to produce 200-500 micron pores in one end after firing. The specimen was implanted into the jawbone of a dog. A very strong bond, believed to be mineralized bone, developed between the implant and the jaw after 10 weeks.

Considerable work on dental implant material comprising an acrylic polymer mixed with organic bone has been done by M. Hodosh. See, for example, U.S. Patents No 3,609,867 and 3,789,029. In the latter patent, Hodosh describes a process for obtaining increased porosity near the outer surface of the polymer implant, where such porosity is most beneficial, by adding a measured amount of N-tributyl phosphate (a blowing agent) to a mixture of polymethacrylate, grate bone, and a foaming agent. The total mixture is polymerized in a mold at 300°F for 30 minutes. After removal from the mold, the processed implant has an outer skin that must be removed by suitable procedures, such as sand-blasting, to expose the porosity caused by the N-tributyl phosphate. According to Hodosh, when the prosthesis is implanted, tissues penetrate the pores to effect a secure fibrous interlock between the implant and the surrounding periodontal membrane. With such a blowing agent no predictable or standard pore size can be achieved, however.

Despite the progress in ceramic and polymer plastic implants and prosthesis outlined above, there still exists a need for a plastic implant having standardized pore size (e.g., a desired hole, any dimension, uniformly distributed, every time) and with no toxicity. In addition, there is a need for a variety of porous plastic implant designs adapted for use in widely different jawbone configurations where no teeth exist (for example, narrow ridge implants, implants near maxillary sinuses, and implants in regions of inadequate alveolar height).

The present invention provides a method of fabricating plastics endosseous implant comprising the steps of:

(a) preparing a replica mold corresponding to the desired shape of the endosseous implant,

(b) attaching to the interior surface of the mold a layer of water-soluble crystals of a particle size corresponding to a pore size desired in a surface region of the implant,

(c) introducing polymerizable material, e.g. acrylic polymer and monomer mixture, substantially to fill said mold,

(d) curing the material in said mold to form the implant,

(e) removing said implant from said mold, and

(f) leaching said water-soluble crystals from said implant.

If desired, the particle size of the crystals may be chosen to produce a predetermined pore size or sizes in the range of from 50 microns to 400 microns and a controlled degree of porosity such that upon insertion into an implant site, such surface portions will be particularly and selectively receptive to the development of the desired type of fibrous connective attachment (e.g., either "soft" connective tissue or "hard" bony tissue) to the contiguous host tissue of the implant site.

Accordingly it is now possible to produce implants having a standardised pore size and the present invention therefore includes a plastics endosseous implant adapted for tooth replacement in a living being, said implant comprising a surface portion having exposed interconnected pores adapted to promote only connective tissue ingrowth from surrounding sub-epidermal and osseous environments, said porous surface portion having preselected pore sizes restricted to the range of from 50 to 150 microns, and said interconnected pores in said surface portion extending to a depth of at least two millimeters. Equally, the invention includes an endosseous non-toxic polymer plastics implant comprising a porous surface portion adapted to mate with a corresponding bone implant site in a living being, said porous surface portion having pore sized restricted to the range from about 200 microns to about 400 microns, a porosity restricted to the range from 50 percent to 75 percent, and a depth of at least two millimeters.

For example, the method of the present invention can provide a tooth root implant having a predetermined porosity in the areas exposed to alveolar and gingival environments. The surface of the implant tooth root, whether the implant is a replica of an extracted root or is a preformed shape to suit the site of a missing tooth, should have a pore size specifically adapted to promote ingrowth and adhesion of periodontal membrane tissues in the portion within the jawbone socket and adapted to encourage ingrowth of soft tissue at and below the gum line.

On the other hand, implants intended to be inserted into direct contact with, or to replace, bony parts of the body should have a larger

pore size (at least 150 microns) that has been found essential to promote hard bone cell ingrowth into the intraosseal portion of the implant.

5 Such an implant may be prepared by adding a completely non-toxic, water soluble, crystalline material (e.g. sodium chloride or sugar) to a powdered acrylic polymer, the volume ratio of crystalline material to polymer being equal to the desired porosity of the finished implant. 10 The particle size of the crystalline material, which preferably is sodium chloride, should be preselected to be the same as the desired pore size of the implant material.

15 It is important that the acrylic monomer have no added promoter or catalyst which could cause a toxic reaction at the implant site. The above mixture is then moistened to a suitable consistency with liquid monomer and poured into a mold that has been suitably prepared by a technique as described in detail below. The mixture may fill the mold or, 20 alternatively, the mixture may be poured around a previously placed reinforcing member of metal, hard nonporous acrylic plastic, or other suitable material that may even include a processed natural root of a previously extracted tooth for which the implant is to be a replacement. Also, instead of having a reinforcing core, the mixture of salt and acrylic polymer-monomer can be reinforced by adding carbon fibers. 25

30 If the implant is intended to be a replacement for a tooth root, a pin of either hard plastic or metal may be incorporated in the mold for securing a subsequently placed tooth cap. Alternatively, the tooth crown portion may be molded integrally with the root by filling the top portion of the mold with pure acrylic polymer-monomer mixture to form a hard non-porous tooth crown portion. 35

40 After the mold is filled, the plastic mixture may be polymerized by placing the mold flask in boiling water for a suitable time (usually about 10 minute), as is well known in the art. The solidified implant is then removed from the mold. 45

50 During the polymerizing process a thin plastics skin forms over the portion composed of salt and plastic mixture, thereby sealing the salt inside the surface. This skin must be removed, preferably by sandblasting, to expose the surface salt crystals. The salt is then leached out by placing the replica in boiling water again for about 4 to 15 minutes. This simultaneously sterilizes the replica, which is then ready for immediate insertion into the previously prepared implant site. 55

60 As indicated above, an important part of the method of the present invention is the proper preparation of the mold surface in those regions of the replica implant that are to have a porous surface. It has been found that without such preparation, the surface region of the polymerized salt-plastic mixture has a defi-

ciency of salt crystals, thereby reducing or eliminating the porosity in the precise location where maximum porosity is desired. According to the method of the present invention, therefore, a preliminary coating of the leachable salt or sugar crystals is attached selectively to the portions of the mold surface prior to filling the mold with the plastic mixture. 70

75 The procedure for attaching the crystals to the mold surface may be accomplished by any one of several alternative methods that also include coating the mold with a conventional release agent to facilitate removing the finished replica from the mold. A well-known release agent used in dentistry is sold under the name "Mar-va-foil", but any similar preparation may be used instead. 80

85 Usually, a thin coating of the release agent alone will be applied to the entire inside surface of the mold, but in one method, salt crystals having a particle size equal to the desired pore size can be mixed with the release agent until it is saturated and the resulting mixture applied to those regions of the mold where a porous surface of the replica is desired. When the release agent dries, a dense layer of salt crystals will be attached to the selected portions of the mold surface. The mold is then ready for the plastic casting steps described previously. 90

95 In another method of mold preparation, the entire inner surface of the mold is coated with a release agent. An acetate cement, is thinned with a solvent such as acetone or methyl ethyl ketone to increase its flowability and is then painted over the release agent in the region where porosity is desired. Salt crystals of desired size are sprinkled onto the thinned glue while it is still tacky. When the cement dries, a dense coating of salt crystals of the desired size will be attached to the selected areas of the mold, ready for the plastic mixture to be cast. 100

105 Instead of mixing the salt in an acetate cement or pre-mixing it in the release agent, the crystals can simply be sprinkled on the release agent (or on a cement coating on top of the release agent) immediately after it has been coated on the mold surface and while it is still tacky. The technique is particularly useful when the entire surface of the replica is to be porous. 110

115 Another method of attaching leachable crystals to the mold surface comprises coating the inside of the mold with mineral oil, preparing a saturated solution of sodium chloride in hot water, coating the oil layer with the saturated saline solution, and placing the mold in an oven to evaporate the water. It has been found that if salt crystals of the desired size are used to make the saline solution and if the solution is so saturated that crystals of that size remain undissolved, then the additional crystals formed when the water evaporates are also generally of that same size. Although the mechanism by which this occurs is not fully 120 125 130

understood, it is believed that the excess crystals in the solution may serve as "models" for the other crystals that precipitate from the solution as the water evaporates. Regardless of the reason, this method also results in a dense layer of salt crystals attached to the mineral oil coating, which acts as a release agent for the subsequently cast plastic mixture.

With any of the preceding mold preparation techniques, a cast polymethyl methacrylate implant can be prepared which has high surface porosity of a predetermined pore size for creating the most effective bond with the surrounding host tissues while permitting the interior portion of the replica body to be made with reduced porosity or even nonporous for increased strength, as required by a given implant application.

Further details regarding the replica implants and their method of fabrication will be provided in the following description of the preferred embodiments in conjunction with the accompanying drawings.

Figure 1 is an enlarged side elevation of a composite hard plastic crown and porous plastic root tooth implant in a lower jaw of normal alveolar bone height, showing the mandibular bone in cross-section;

Figure 2 is a view similar to Figure 1 but showing a plastic tooth implant cemented into the alveolar bone socket;

Figure 3 is a view similar to Figure 1 but showing an implant with a hard plastic core in a porous plastic root;

Figure 4 is similar to Figure 3 but showing an implant with a hard plastic root coated with porous plastic;

Figure 5A is a view similar to Figure 4 but showing a tooth implant formed from a natural extracted tooth with its root coated with porous plastic;

Figure 5B is an enlarged view of the alveolar environment within the circle of Figure 5A;

Figure 6 is an enlarged side elevation of a natural mandibular tooth in a jaw having an inadequate alveolar bone height;

Figure 7 is a view similar to Figure 6 but showing the same tooth following extraction, coating of the root with porous plastic, reinsertion, and subsequent stimulation of connective tissue ingrowth to create a normal alveolar height;

Figure 8 is a view similar to Figure 7 but showing a plastic replica tooth implant having a hard plastic crown and porous plastic root set into a built-up alveolar ridge of synthetic bone;

Figure 9A is a view similar to Figure 8 but showing a porous plastic tooth root implant having a hard plastic core;

Figure 9B is a top view of the embodiment of Figure 9A;

Figure 10 is a side elevation of *in situ* replacement by porous plastic implant material of a bony periodontal defect in order to build

up lost alveolar height;

Figure 11 is a side elevation of a multiple tooth replacement by means of a synthetic alveolar ridge implant in a lower jawbone;

Figure 12 is a cross-section of Figure 11 taken in the direction of arrow 12-12;

Figure 13 through 18 illustrate the steps of an alternate method of correcting for inadequate alveolar bone height, in which Figure 13 shows a natural tooth *in situ*;

Figure 14 shows the mandibular socket of Figure 13 after extraction of the tooth;

Figure 15 shows a combination drill and tap in position to prepare a deeper, threaded tooth support socket;

Figure 16 shows the drill/tap completing the new socket;

Figure 17 shows the prepared threaded socket after the combination drill/tap has been backed out;

Figure 18 shows a prefabricated threaded porous plastic tooth support post inserted into the prepared socket, ready to receive a hard plastic tooth crown;

Figure 19 shows a set of prefabricated threaded porous plastic tooth support posts in a graduated range of sizes for use in different regions of the mouth and in different sizes of jawbone;

Figure 20 shows a threaded plastic type of tooth implant *in situ* with the tooth crown in place;

Figure 21 is a side view in partial section of the threaded support post of the tooth implant of Figure 20;

Figure 22 is a bottom view of the threaded support post 15 of Figure 21;

Figure 23A, B and C show prefabricated threaded root implants in a range of sizes to suit different bone ridge formations.

Figure 24 is a side elevation of a hard-plastic screw post set in a porous plastic root implant for receiving a tooth cap;

Figure 25 shows a temporary screw plug fitted in the porous plastic root implant of Figure 24;

Figure 26 is a top view of the implant of Figure 25;

Figure 27 is a side view of a blade-type implant for use in molar replacement;

Figure 28 is an end view of the implant of Figure 27;

Figure 29 is a top view of the implant of Figure 27;

Figure 30 is a side view of a blade-type implant for use in regions where there is less bone available than for the implant of Figure 27;

Figure 31 is a side view of another blade-type implant for use in front tooth replacement;

Figure 32 is a side view of a blade-type implant design for use in replacing an upper tooth near a maxillary sinus;

Figure 33 is an end view of the implant of

65 of a bony periodontal defect in order to build

70

75

80

85

90

95

100

105

110

115

120

125

130

Figure 32;

Figure 34 is a bottom view of the implant of Figure 32;

Figures 35A and 35B are progressively smaller-sized versions of the implant of Figure 32 for use in smaller jaws with smaller maxillary sinuses;

Figure 36 is a side elevation of another form of blade-type tooth support implant;

Figure 37 is a front elevation of the implant of Figure 36;

Figure 38 is a top view of the implant of Figure 36;

Figure 39 is a side elevation of a conical form of tooth support implant;

Figure 40 is a front elevation of the implant of Figure 39;

Figure 41 is a top view of the implant of Figure 39;

Figure 42 is a side elevation of still another blade-type tooth support implant having a flared lower portion;

Figure 43 is a side elevation of the tooth support implant of Figure 42;

Figure 44 is a top view of the tooth support implant of Figure 42;

Figure 45 is a side view of a lower jawbone having a diseased or otherwise defective section replaced by an interlocking porous plastic implant;

Figure 46A is a side view of a lower jawbone of which a major portion has been replaced by a replica plastic implant;

Figure 46B is an enlarged sectional view of the mortise and tenon joint between the host bone and the implant of Figure 46A;

Figure 47 illustrates an alternative form of attachment of a plastic mandibular defect replacement to the host bone by means of acrylic screws and plates;

Figure 48 is a top view of a mandible having plastic condylar head implants at each hinge joint;

Figure 49 is a side elevation of a cast polymer composite joint prosthesis having a solid plastic ball joint head, a small pore porous plastic midbody, and a large pore porous plastic fixation pin;

Figure 50 is an alternate embodiment of a composite plastic joint prosthesis having large bone ingrowth holes in the fixation pin;

Figure 51 shows a joint prosthesis inserted in the adjoining end of a limb bone;

Figure 52 shows a hard plastic ball for use as a condylar head in a joint prosthesis;

Figure 53 is a photomicrograph at approximately 3X of a chlorine scan of a sample of porous plastic having pore sizes of 100-150 microns;

Figure 54 is a photomicrograph at 40 X of a sample of porous plastic having pore sizes of 75-150 microns;

Figure 55 is a photomicrograph at 25 X of a sample of porous plastic having pore sizes of 300-400 microns;

In the detailed discussion that follows, various applications of the invention to dental implant design will be described, followed by examples of bone implants and prosthetic devices, and concluding with a description of alternative methods for making the previously described implant structures and for emplacing them in the intended body location. In the drawings, the same or similar features are identified by the same reference number in each figure for convenience.

The need for a tooth implant may arise from a variety of causes, and each situation may require a different implant structure. In addition, the type of tooth being replaced (e.g. molar, bicuspid or incisor) and its location in the mouth will affect the required shape of the implant support or root, both because each tooth encounters a different stress and because the alveolar ridge at the front of the mouth is normally narrower than at the rear. The location of the maxillary sinus cavities in the upper jaw may also affect the shape of the implant support. Consequently, the present invention contemplates a range of sizes, shapes, and constructions, as illustrated by the following drawings of tooth implant embodiments. All of the different designs incorporate, however, the underlying concept of pore size and porosity depending upon the type of tissue ingrowth that is desired.

Figures 1 to 5 illustrate several embodiments for use when replacing an existing tooth in a socket having normal alveolar bone height. In these drawings, as well as in all subsequent drawings representing *in situ* conditions, the anatomical details are rendered in a formalized schematic manner for simplicity.

Referring to Figure 1, a plastic replica tooth implant 101 comprises a hard plastic tooth crown 102 integrally molded with a porous plastic tooth root 103. The term replica will be used to refer to a tooth implant or other plastic implant structure that has the exact size and shape of the tooth or bone that it replaces. Such a replica will normally be cast in a mold that has been prepared using the original tooth or bone as the model for the mold. In this case the tooth replica 101 has been set in an alveolar cavity 104 of the lower jawbone or mandible 105. The jawbone is composed of a cortical or outer bone portion 106 and an inner spongy medullary portion 107. The example of Figure 1 illustrates a mandible having a normal alveolar height; i.e., the tooth socket extends well up near the top of the root portion of the implant. Above the jawbone lies the dermis 108 with the outer covering of the gums or gingiva 109 extending up to the top of the porous portion of the implant.

Figure 1 illustrates the situation after the implant has become fully attached to the alveolar socket by means of a periodontal membrane 110 and to the gingiva by an epithelial attachment 111. In addition, hard bone in-

growth 112 has occurred through two holes 113 and 114 drilled in the root portion of the replica, each hole being approximately 2 to 3 millimeters in diameter. Finally, fibrous tissue ingrowth 115, that constitutes an extension of the periodontal membrane, has occurred between the alveolar bone and the intermediate root portion of the tooth replica. As a consequence, the tooth implant is firmly attached both to the underlying jawbone and to the overlying gingiva in a manner completely simulating the environment of a natural healthy tooth.

Figure 2 illustrates a replica 101 that is the same as the replica of Figure 1. In this case the replica has been cemented into the alveolar cavity by a suitable cement, such as polymethylacrylate cement, glass-ceramic cement, or a cement known as Kodak 9-10 manufactured by the Eastman Kodak Company. In this embodiment the cement coating in the root portion of the replica provides an initial strong attachment to the jawbone, which is then supplemented over a period of weeks by ingrowth of periodontal tissue as described above.

The next two figures 3 and 4, illustrate two embodiments of a replica tooth implant formed by a two-stage technique. In these embodiments, the root portion is cast first and inserted in the alveolar socket. In the embodiment of Figure 3 the root portion comprises a hard plastic insert 117 that extends, either partially or almost fully, to the bottom of the root and is surrounded by porous plastic 118 as illustrated. The possible range of lengths of the hard plastic insert 117 is shown between the dash line 119 and solid line 120 on the drawing. After the root portion has been installed for a period of several weeks; so that connective tissue has had a chance to develop between the lower root and the alveolar socket and between the gingiva and the upper root, a preformed acrylic crown 121 can be attached to the upper portion 122 of the hard plastic insert that extends above the porous plastic root by any conventional cementing technique. In this way the implant supporting or root is protected by the adjacent teeth against the normal stress exerted on a tooth grown during the critical period while the attachment membranes are forming between the root and the surrounding socket and gingiva. If desired, any conventional crown material other than acrylic, for example a porcelain jacket or acrylic veneers, can be used for the finished tooth.

In Figure 3, the hard plastic pin 122 provides reinforcement in the upper portion of what is primarily a porous plastic root. In the embodiment of Figure 4, on the other hand, a hard plastic root replica 123 is coated with a relatively thin porous plastic outer covering 124 to provide a surface that will promote ingrowth of the periodontal membrane and the connective tissue at the gingival contact area.

The embodiment of Figure 4 is like the Figure 3 embodiment in that the tooth crown 121 is cemented to the exposed mounting post of the hard plastic root 123 after the root has become fixed in the alveolar socket. This process normally takes only a few weeks at the most.

Occasionally in cases of gum disease, a sound natural tooth will become loose in its socket. In such a situation, it may be possible to use the tooth itself as the base for a dental implant. Figures 5A and 5B show a natural tooth 125 that has been extracted, the root portion 126 etched with phosphoric acid, a thin coating 127 of porous plastic applied to the root portion, and the tooth reinserted in its socket. When this procedure is accompanied and followed by the proper treatment for alleviating the underlying problems of the gum disease, the result is a recreation of the necessary periodontal membrane ingrowth in the lower root portion and epithelial attachment of the gingiva with the upper portion of the porous plastic coating to produce firm fixation of the tooth in its socket and a return to normal and healthy periodontal conditions.

As stated above, the tooth implant embodiment of Figures 1 and 2 is formed as an exact replica of a natural tooth by using the latter, immediately following the extraction, as a pattern for a plaster mold fashioned by conventional flasking techniques. After the mold has set, the root portion is filled with a flowable mixture of acrylic plastic and leachable crystals of predetermined size. The crown portion of the mold is then filled with pure acrylic polymer/monomer mixture and the entire flask placed in boiling water until the replica casting has hardened. The cast replica is then removed from the mold and the crystals leached from the root, thereby creating the desired porosity. The details of the procedure are described in the final portion of the specification.

The two-step procedure for the implant of Figure 3 differs from the one-step implants above in that a plaster mold on only the root of the extracted tooth is made in the first step. A hard (solid) plastic pin is placed in the mold before filling the remainder with the mixture of plastic and leachable crystals. The lower end of the pin serves to reinforce the root structure, while the upper end extends above the root to act as a mounting post for the preformed crown that is installed in the second step of the procedure.

In making the embodiment of Figure 5A, the tooth root, after it has been etched with phosphoric acid, is coated with wax and then pressed back into its socket. In this way, the wax coating takes an exact snug impression of the tooth socket. Then the plaster mold is made in the usual way. The tooth is removed from the mold, dipped in boiling water to remove the wax, and replaced in the mold. The space previously occupied by the wax is then filled with a mixture of polymer, monomer, and

leachable crystals, which is then processed to form the porous plastic coating. Instead of, or in addition to, premixing the leachable crystals with the polymer-monomer mixture, the crystals are attached to the interior surface of the mold before the mixture is added, thereby increasing the porosity at the surface.

The embodiment of Figure 4 is made in the same way as that of Figure 5A except that the etched root of the natural tooth may be used as a pattern to make a hard plastic replica, formed with a crown mounting post at the top, that becomes the core of the implant. Alternatively, the hard plastic core may be selected from an assortment of prefabricated root shapes and sizes. This embodiment provides a structural strength comparable to the natural tooth by using a maximum amount of hard plastic in the root portion, and can be used when the natural tooth is not suitable (because of decay, fracture, or other defects).

Turning next to Figures 6 to 9, these figures illustrate various implant techniques and embodiments for use in situations where the alveolar height is abnormally low. Figure 6 depicts a natural tooth 128 *in situ* in the alveolar cavity 129 of a mandible 130, having cortical bone portion 131 and inner spongy bone portion 132. In Figure 6 the height of the alveolar bone is abnormally low, causing the gums (gingiva) 133 and the underlying dermis 134 to recede, thereby exposing intermediate root portion 135 between the tooth crown portion 136 and the lower root portion 137 that is held in the socket by periodontal membrane 138. This is an atrophied condition of the periodontal environment that causes gradual deterioration and ultimate loss of the natural tooth, followed by a strong tendency for alveolar resorption unless appropriate dental countermeasures are undertaken promptly.

Assuming that the atrophy of the jawbone and resulting damage to the natural tooth has progressed to the point where extraction of the tooth is required, Figures 7-9 illustrate three approaches to the problem of rebuilding the alveolar ridge and fixating a replacement tooth. In Figure 7, the natural tooth has been removed, treated in exactly the same way as the embodiment of Figure 5, and replaced in its socket. The porous plastic coating 139 is strongly bonded to the etched root 140 and, in turn, provides a superior surface for encouraging the ingrowth of periodontal membrane cells in the alveolar socket.

At the time that the tooth is extracted, the dermis is also undercut along each side of the jawbone, as indicated by lines 141 and 142. Then after the treated tooth has been replaced in its socket, the dermis and overlying gingiva are pulled up to the normal gum line of the tooth and sutured in place. Within a few weeks, new periodontal membrane tissue 143 will grow upward from the jawbone and attach firmly to the porous plastic surface on the

previously exposed intermediate portion of the tooth root. Concurrently, the gingiva will form an epithelial attachment to the upper margin of the porous plastic coating. Thus, the reparative approach taken with this embodiment is to encourage the formation and attachment of fibrous connective tissue to the previously exposed root portion of the natural tooth. After a period of natural growth and adaption, a desired normal gingiva condition results, as shown by gingiva 132 disposed at the base of crown portion 144, with the root portion properly embedded in alveolar cavity 129 with fibrous connective attachments 138 in alveolar cavity 139 and new connective tissue 143 creating the effect of a normal alveolar ridge.

Figure 8 shows an embodiment of a tooth implant 145, of the same type as that of Figure 1, that has been inserted in alveolar cavity 129 to replace the natural tooth shown in Figure 6. This embodiment is formed as an exact replica of the natural tooth by using the latter as a model for a plaster mold fashioned by conventional flasking techniques, just as described in connection with Figure 6. Thus, replica embodiment 145 of Figure 8 comprises a hard (i.e. solid) cast polymer crown 146 integrally formed with a porous plastic root portion 147. In this case, however, the alveolar ridge has been built up artificially at the time of inserting the implant by packing synthetic bone 148 around the exposed intermediate portion of the root.

The synthetic bone used to form the alveolar ridge in this and following examples preferably is composed of large pore cast porous polymer (e.g. polymethyl methacrylate) having pore sizes in the range of 200-400 microns. Other conventional synthetic bone materials can be used, however, such as porous ceramic titanium dioxide ( $\text{TiO}_2$ ), glass ceramic, calcium phosphate ( $\text{Ca}_3(\text{PO}_4)_2$ ), or biodegradable polymer (lactic acid).

After the dermis has been undercut and the gingiva pulled up and sutured in place, new connective tissue attachments 149 and 150 will occur between the implant and the synthetic alveolar ridge and between the synthetic ridge and the contiguous dermis, respectively.

Referring to Figures 9A and 9B, the two-step procedure described in connection with Figures 3 and 4 can also be used in the situation of inadequate alveolar height. The example of Figures 9A and 9B uses a replica root embodiment similar to that of Figure 3, with a built-up alveolar ridge of synthetic bone, as in the example of Figure 8. The replica root includes a solid plastic insert 151, having an exposed crown mounting post 152 and a reinforcing root portion 153 surrounded by a porous plastic jacket 154. Two holes 155 and 156 are provided for additional fixation by means of hard bone ingrowth.

As in the case of the one-step implant, the

dermis is undercut and the gingiva pulled up around the upper margin of the porous plastic jacket, where it is held in place by sutures 157.

In some cases, as shown by Figure 10, alveolar bone resorption will create a trough 158 around the natural tooth 159. This situation can be treated in two ways. In the first procedure, porous synthetic bone material 159A of the invention is packed around the intermediate portions of roots 160 and 161 to replace the lost alveolar bone. The second procedure is used when the tooth is loose and includes the additional steps of first extracting the tooth, etching the root, sealing the end of the root canal, and replacing the tooth in its socket before packing the synthetic bone material of the invention around it. The root etching procedure produces a roughened surface that promotes a good attachment to the periodontal membrane. If necessary, a porous plastic coating can be added, according to the previously described techniques of the invention. As in the procedure illustrated by Figures 7-9, the dermis should be undercut and the gingiva raised to the former gum line and sutured until connective tissue ingrowth has occurred.

The previous examples have all dealt with replacement of a single existing tooth by using the extracted tooth, either as a pattern for a cast plastic replica or, by suitable treatment, as its own replacement. Figures 11 and 12 illustrate a procedure for replacing a group of from two to five teeth by means of a multiple implant in two steps or stages. This procedure can be used both in the situation where all the replaced teeth are missing and there is very little alveolar bone height or where the group of teeth are all periodontally involved and must be removed.

In the first stage, an artificial alveolar ridge 162 of porous plastic is cast, using a wax impression or similar material as a pattern for a plaster mold by conventional techniques. Solid plastic inserts 163 may be cast integrally with the artificial ridge or may be cemented in place subsequently, as desired. The entire ridge structure is then placed in mating contact with mandible 164, (having alveolar canal 165) and the previously undercut gums 166 sutured in place around the inserts, leaving crown mounting posts 167 exposed.

Because the gingiva will not form an epithelial attachment with the smooth surface of the inserts, the exposed portions between the top of the artificial ridge and the base of the mounting posts should be covered with a suitable material 168 such as nylon velour or polyester mesh. Alternatively, these portions of the inserts 163 can be provided with porous surface (50-150 microns pore size) by the methods of this invention. Conversely, it should be mentioned that gingival attachment in any of the other described examples can be obtained through the use of nylon velour or

polyester mesh, if desired.

After the implant has been in place for several weeks so that firm attachments have formed between the mandible and the large pore artificial ridge (hard bone ingrowth) and between the gingiva and the velour, mesh or small pore insert surface (soft tissue ingrowth), a one-piece group of solid plastic crowns 169 can be cemented onto the mounting posts. It will be appreciated, of course, that the crowns can be made of any other suitable conventional dental material and also that the artificial ridge can be made of any of the synthetic bone materials previously described. Furthermore, the artificial ridge building technique can be used along without insert teeth to provide support for a denture.

Instead of building up an artificial alveolar ridge to provide sufficient socket depth for proper support of implant teeth, the sockets themselves can be deepened by the procedure illustrated by Figures 13 to 17 and a prefabricated implant root installed as shown in Figure 18. In Figure 13, a natural tooth 170 is in an abnormally low alveolar socket 171 of a jawbone 172 having an alveolar canal 173. According to the illustrated procedure, the tooth is extracted (Figure 14), and a combination drill and tap 174 mounted in a slow speed hand-piece 175 is inserted into the alveolar socket (Figure 15), run down to the desired depth (Figure 16), and then backed out leaving a deepened, threaded socket 176 (Figure 17). A mating threaded plastic insert 177 (Figure 18) having a suitable porous surface is then threaded into the socket. The insert has a suitable crown mounting post 178 for subsequent attachment of a hard plastic crown 179 (shown in dashed lines).

Since the threaded plastic insert is sized to match the drilled and tapped hole, it is possible to provide an assortment of preselected insert sizes, as shown in Figure 19, to correspond to similar sized taps for a full range of tooth and alveolar site sizes. The threaded inserts will simplify the job of preparing a tooth implant in many cases when there is an existing tooth as well as in those situations where the tooth is missing.

Additional embodiments of threaded porous plastic inserts are shown in Figures 20 to 23. In Figure 20, a threaded insert 180 of porous plastic is shown in place in a jawbone 181 surmounted by dermis 182 and gingiva 183. A solid plastic crown 184 is cemented onto mounting post 185 at the top of the insert. If desired, the mounting post portion of the insert can be made of integrally molded solid plastic instead of porous plastic. Not only does this combination provide added strength but also the smooth surface of the solid plastic post will inhibit formation of epithelial attachment for the gingiva above the upper margin of the porous plastic cylindrical portions of the insert.

Features of this embodiment include a flared lip 186 at the top of the threaded portion that provides additional anchoring after the natural bone has grown in above it, as shown in Figure 20. Another feature is an axial centre hole 187 (best seen in Figures 21 and 22) that also produces improved anchorage by providing space for the ingrowth of hard bony cells and additional area for periodontal membrane attachment.

Figures 23A, B and C illustrates a range of sizes for this type of implant in which the diameters vary inversely with length so that the surface area will remain approximately constant. Thus, the different sizes are adapted for use in different regions of the jaw, but all provide similar anchoring surface.

In the embodiment of Figures 24 to 26, a tapered large pore porous plastic implant 188 having two transverse bone anchoring holes 189 and 190 is provided with tapered threaded hole 191 for receiving a mating threaded hard plastic mounting post support 192. Insert 188 is set into alveolar bone 193 so that its top surface is slightly below the top of the alveolar ridge, thereby encouraging the natural bone to grow over the implant, firmly locking it in place. The threaded plastic insert is cemented in the threaded hole with its mounting post 196 extending above the gingiva to receive a crown (shown in dashed lines) after the implant has become securely attached to the jawbone by hard bony ingrowth. Alternatively, the implant can be made of small pore (50-150 micron) porous plastic. In that case, it will become attached to the jawbone by means of a softer periodontal membrane, which provides a shock absorbing medium.

In situations where there are no neighbouring teeth to shield the mounting post during the period that the implant is becoming attached to the host bone, a temporary hard plastic or metal plug 198 having a top slot 199 can be screwed into the threaded hole, with its top surface flush with or below the surrounding gingiva 195. After the implant is set, the plug is removed and the permanent insert screwed in and cemented in place.

The porous plastic material used with the present invention is also suitable for making blade-type implants, and Figures 27 to 44 illustrate a number of different embodiments. In Figures 27 - 29 a wide plate implant 200 of small pore plastic has an integrally cast solid plastic mounting post insert 201. The implant site is prepared by cutting a thin slot in the jawbone 202 deep enough so that the top of the implant blade will be below the top of the alveolar ridge. Dermis 203 and gingiva 204 are then sutured snugly against the tapered collar 205 to allow the gingiva to become attached to its porous surface. Subsequently, a crown 206 (shown in dashed lines) can be cemented onto mounting post 207.

Blade-type implant 200 has four bone

ingrowth holes 208 and is particularly suited by shape and size for use in the rear of the lower jaw. Smaller and narrower blade type implants 209 (Figure 30) and 210 (Figure 31) are suitable for bicuspid and incisor supports, respectively.

In the upper jaw (maxilla), the presence of the maxillary sinus cavities create a problem in finding sufficient bone to support a tooth implant. This problem is solved by the curved-blade designs of Figures 32-34, in which a blade-type implant 211 has a curved inner edge 212 to conform to the curve of a maxillary sinus cavity 213. This type of implant can also come in a range of sizes as shown by implants 214 and 214B of Figures 35A and 35B, respectively.

Still further implant shapes for crown mounting post supports are shown in Figures 36 to 44. Implant 215 (Figures 36 - 38) has an arrowhead shape, implant 216 (Figures 39 - 41) has a conical shape, and implant 217 (Figures 42 - 44) has a fish-tail shape.

As mentioned earlier, the same porous plastic implant material used for tooth implants can also be used for bone implants, bone replacement, and joint prostheses. The primary difference is in pore size, since hard bone ingrowth requires pore sizes of at least 200 - 400 microns. Referring to Figures 45 - 48, there are shown various techniques for mandibular repair that are equally useful for bone repair in other parts of the body. In Figure 5 a porous plastic mandibular replacement section 218 is locked into mandible 219 by dovetails 220 and 221. It will be appreciated that the dovetail joints are actually a relatively tight fit and additional may be cemented in place for adequate fixation until bone ingrowth can occur.

A large mandibular segment 222 (Figures 46A and B) is joined to the host hinge bone section 223 by a mortise and tenon 224 and 225. As before, the joint can be cemented for stabilization until bone ingrowth takes place. In Figure 47 a bone insert 226 is held in place by acrylic screws 227 through acrylic plates 228 and also by cement, if desired. In Figure 48 plastic condylar heads 229 have been implanted at each hinge of mandible 230.

The polymethyl methacrylate material described herein is also useful for making hip joint or other joint prostheses. In Figure 49, a prosthesis of conventional form has a hard, solid plastic head 231, a small pore (50-150 microns) plastic midbody 232, and a large pore (200 - 400 microns) plastic fixation pin 233. The small pore midbody provides a surface for ligament attachment, and the large pore pin provides a surface for hard bony attachment when the pin is inserted in the end of a leg bone 234, for example (see Figure 51). An alternate joint prosthesis of conventional design is shown in Figure 50 with a smooth hard non-porous condylar head 235, a small

pore midbody 236 and a large pore fixation pin 237 having large bone ingrowth holes 238. In Figure 52 a hard plastic ball 239 has a porous cover 240.

5 It should be understood that in referring to porous plastic portions, whether small pore or large pore, the porosity can either extend all the way through the portion or be only in a surface layer, depending on the strength requirements of the implant or prosthesis.

10 An important aspect of the present invention lies in the selection of proper pore size for the desired type of tissue attachment, whether soft connective tissue or hard bone tissue. Since the desired attachment of the replica embodiments of Figures 1-9 is by relatively soft fibrous connective attachments 24 and 28, the pore size of the sheath portion is preselected in the range from about 50 microns to about 150 microns, while the degree of porosity is preferably in the range from about 50 percent to about 75 percent by volume.

25 In recent tests on rats conducted under the direction of the applicant, it has been discovered that the choice of pore size is critical in determining the type of cell ingrowth that will occur in porous polymethyl methacrylate (hereinafter called porous PMM) material. In these tests, two series of small samples of porous PMM having pore sizes predominantly in the ranges 50-150 microns and 200-400 microns, respectively, were implanted in rats in four different site environments; subcutaneous, intramuscular, intracerebral and intraosseous. The subcutaneous implants were retrieved at intervals up to 70 days, but the implants in the other sites were kept in place a maximum of only 30 days.

40 In each of the three non-osseous sites the surrounding tissues were firmly attached to the implants of both pore sizes, but there was no evidence of either cartilage development (chondrogenesis) or bone development (osteogenesis) at any of the nonosseous implant sites. At none of the sites was any infection or any other pathological symptom noted. At the intraosseous sites, on the other hand, there was found in all cases a reparative bone formation adjacent to the implanted specimens. Within the pores of the material, however, bone cells were found only in the large-pore (200-400 microns) specimens. In the small-pore (50-150 microns) specimens only soft tissue ingrowth was evident. These tests indicate, therefore, that the type of connection between bone and an intraosseous implant can be controlled by preselecting the pore size of the implant material in the regions of the implant surface that are contiguous to the host bone.

65 Referring again to the embodiment of Figures 1-9, therefore, by preselecting the surface pore size of the entire root portion of the implant to be in the range from about 50 microns to about 150 microns, the growth of soft connective tissue into both the upper root surfaces and the intraosseal root surfaces can be assured.

rons to about 150 microns, the growth of soft connective tissue into both the upper root surfaces and the intraosseal root surfaces can be assured.

The method of fabrication of the implant tooth replica in each case is as follows: 70

(1) the natural tooth is extracted;  
(2) the natural tooth is used, by well-known conventional dental laboratory techniques (e.g. by flasking) to form a replica mold; 75

(3) a conventional and well-known mold release agent is applied in the mold;

(4) a foundation for the porous portion of the replica root section is prepared by:

(a) determining the desired porosity or porosity range, and degree of porosity, 80

(b) selecting water soluble salt crystals having crystal sizes corresponding to the aforesaid pore sizes,

(c) attaching a layer of said salt crystals to selected portions of said release agent coating on the inside of the mold, 85

(d) mixing acrylic polymer and monomer with said salt composition in volume proportions corresponding to said desired degree of porosity to provide a molding composition of the required volume, 90

(5) introducing said composition into the root portion of said mold;

(6) adding additional acrylic polymer and monomer to fill said mold, including said crown portion; 95

(7) heat polymerizing the ingredients in said mold;

(8) extracting the casting from said mold; 100

(9) sandblasting or otherwise removing the surface skin from the root portion of the casting to expose the salt particles;

(10) boiling the casting in water from about four to fifteen minutes to leach out said salt to leave pores and voids in the place thereof; and 105

(11) pressing said porous casting into the extraction socket formerly occupied by the natural tooth.

The salt crystals may be any water soluble salt. Sodium chloride is preferred because of price and ease of removal, and especially because it is completely non-toxic and, in fact, residual amounts in the centre portion of the root may benefit the healing process. On the other hand, any leaching crystalline material capable of more or less precise size classification may be used as long as it is non-toxic and has chemical compatibility with the plastic employed. The leaching medium may be other than water, likewise depending on its compatibility with the plastic and its non-toxicity. 115

As examples of the type of pores and porosity that are obtained by the above described casting techniques, micro-photographs of samples of polymethyl methacrylate materials made with three different sizes of salt crystals are shown in Figures 53-55. Figure 53 is a so-called chlorine scan at approximately 3X power of a sample of sodium chloride crystals having 120 130

a size range of 100 - 150 microns. The photograph was made before leaching out the salt crystals, which show up as light spots on the dark background.

5 Figure 54 shows a sample, after leaching, at 40X power that was made with salt crystals having a size range of about 75 - 150 microns. Figure 55 shows a similar sample at 25X power that was made with salt crystals in the size range of 300-400 microns. All samples were made with equal volumes of salt crystals and polymer.

10 In view of polymethylmethacrylate's proven adaptability for implants it is recognized as preferred for the instant invention at the present time. Recognizing, however, the rapid advance of scientific knowledge and expertise, it may well be a very short time that another, readily available, material may be used for the purpose of the present invention and perhaps even with greater advantage.

15 Preferred embodiments of the invention have been specifically described which can be performed quickly and easily by a dental or orthopedic surgeon or technician during an operating situation when the allowance time between the removal of a tooth or other surgical procedure and the fitting of the completed implant is measured in minutes.

20 Moreover it is thereby possible to provide a process for fabricating a polymethyl methacrylate implant structure without using any toxic additives, or any toxic or otherwise dangerous materials to create the desired degree, size and depth of implant porosity.

#### 35 WHAT I CLAIM IS:-

1. A method of fabricating a plastic endosseous implant comprising the steps of:

40 (a) preparing a replica mold corresponding to the desired shape of the endosseous implant,

(b) attaching to the interior surface of the mold a layer of water-soluble crystals of a particle size corresponding to a pore size desired in a surface region of the implant,

45 (c) introducing polymerizable material, e.g. acrylic polymer and monomer mixture, substantially to fill said mold,

(d) curing the material in said mold to form the implant,

50 (e) removing said implant from said mold, and

(f) leaching said water-soluble crystals from said implant.

55 2. A method as claimed in claim 1 wherein said water-soluble crystals are sodium chloride.

3. A method as claimed in claim 1 or claim 2 wherein step (b) comprises painting the root portion of the mold with a layer of acetate cement and sprinkling said crystals on the cement while it is still tacky.

60 4. A method as claimed in claim 3 wherein said layer of acetate cement is peeled from the surface of the replica to expose the water-soluble crystals before said leaching step.

65 5. A method as claimed in claim 1 or claim 2

wherein step (b) comprises coating the interior of the mold with a release agent and sprinkling said crystals on the release agent before it hardens.

6. A method as claimed in claim 1 or claim 2 70 wherein step (b) comprises mixing said crystals with a release agent and painting the mold interior with said mixture.

7. A method as claimed in claim 1 or claim 2 75 wherein step (b) comprises coating the mold interior with a release agent, preparing a saturated aqueous solution of said crystals, coating the layer of release agent with said saturated solution, and heating the mold to evaporate the water from said aqueous solution.

8. A method as claimed in claim 7 wherein said release agent comprises mineral oil.

9. A method as claimed in any one of claims 1 to 8 wherein said leaching step is carried out in boiling water for about 4 to 15 minutes. 85

10. A method as claimed in any one of claims 1 to 9 comprising the additional steps before step (c) of preparing a mixture of acrylic polymer and monomer with water-soluble crystals of a particle size corresponding to a pore size desired in a subsurface region of said implant and in relative proportions corresponding to the degree of porosity desired therein and introducing said mixture into the mold.

11. A method as claimed in any one of claims 1 to 10 comprising between steps (b) and (c), inserting a reinforcing pin in said mold so as to be concealed wholly within said implant when cured. 95

12. A method as claimed in any one of claims 1 to 11 wherein a freshly extracted tooth is used as a master in preparing a replica mold in step (a) corresponding to at least the root portion of said tooth so that the implant molded therefrom is a replica of said root portion. 100 105

13. A method as claimed in claim 12 wherein the cement comprises polymethylacrylate (carboxylate) or a glass-ceramic cement.

14. A method as claimed in claim 1 and substantially as hereinbefore described. 110

15. A method of fabricating a plastic endosseous implant substantially as hereinbefore described with reference to any of the figures of the accompanying drawings. 115

16. An endosseous plastic implant which has been made by a method as claimed in any one of claims 1 to 15.

17. An implant as claimed in claim 16 having an exposed porous surface portion adapted to promote only soft connective tissue ingrowth from both surrounding epidermal and osseous environments, said surface portion having preselected pore size exclusively in the range of from 150 microns. 120 125

18. An implant as claimed in claim 17 wherein said porous surface portion comprises the root portion of a tooth replica.

19. An implant as claimed in claim 17 or claim 18 comprising another exposed surface 130

portion adapted to promote hard bony ingrowth from a contiguous osseous environment, said other surface portion having preselected pore sizes exclusively in the range of 200 to 400 microns.

20. An implant as claimed in claim 19 comprising a joint prosthesis having a condylar head composed of solid plastics, a midbody joined to the head and comprising said first-mentioned porous surface portion, and a fixation pin extending from the midbody and comprising said another porous surface portion, the pore size of said midbody being adapted to permit soft tissue ingrowth for ligament attachment, and the pore size of said fixation pin being adapted to permit hard bony cell ingrowth for endosseous fixation when the prosthesis is implanted in a bone of a living being.

21. An implant as claimed in claim 20 wherein the fixation pin includes transverse bone ingrowth holes.

22. An implant as claimed in claim 21 comprising a hip joint prosthesis or a mandibular prosthesis.

23. An endosseous non-toxic polymer plastic implant as claimed in claim 16 having a surface portion which comprises a porous surface portion adapted to mate with a corresponding bone implant site in a living being, said porous surface portion having preselected pore size in the range from 200 microns to 400 microns, a porosity in the range from 50 percent to 75 percent, and a depth of at least 2 millimeters.

24. An implant as claimed in claim 23 wherein said porous surface portion is formed with a dovetail for making a dovetail joint with the bone implant site.

25. An implant as claimed in claim 23 wherein said porous surface portion is formed with a tenon for making a mortise and tenon joint with the bone implant site.

26. An implant as claimed in claim 16 comprising a support for a tooth crown, said support having a porous surface portion which includes a threaded portion adapted to screw into a tapped alveolar socket, and a crown mounting post at one end of said implant.

27. An implant as claimed in claim 26 wherein said threaded portion is tapered from adjacent the mounting post to a reduced diameter at the other end of the implant.

28. An implant as claimed in claim 26 wherein said threaded portion has a constant mean diameter.

29. An implant as claimed in any one of claims 26 to 28 wherein said porous portion extends through the threaded portion of the implant.

30. An implant as claimed in any of claims 26 to 29 comprising an axial center hole extending inward from an end of the threaded portion to provide space for the ingrowth of hard bony cells.

31. An implant as claimed in any one of claims 26 to 30 comprising a flared lip at one

end of the threaded portion between the threaded portion and the crown mounting post.

32. An implant as claimed in claim 31 comprising an intermediate cylindrical porous portion between said flared lip and said crown mounting post.

33. An implant as claimed in claim 16 comprising a tapered foundation member for an artificial tooth crown support, the foundation member having a tapered threaded hole extending axially inward from a large diameter end, said hole being adapted to receive a mating tapered threaded crown support.

34. An implant as claimed in claim 33 wherein the foundation member is composed of porous plastic having a pore size from 50 - 150 microns.

35. An implant as claimed in claim 16 comprising a support for a tooth crown, said support having a blade portion substantially wider in one dimension than in the cross dimension, said blade portion comprising a porous surface portion of the implant, and a crown mounting post extending from one side of the blade portion.

36. An implant as claimed in claim 35 comprising a tapered plastic collar at the junction of the blade portion and the crown mounting post, said collar having a porous surface adapted to promote an epithelial attachment to surrounding gingiva when the support is implanted into a jawbone of a living being.

37. An implant as claimed in claim 35 or claim 36 wherein the blade portion has a plurality of bone ingrowth holes.

38. An implant as claimed in any one of claims 35 to 37 wherein the side of the blade portion opposite said one side is curved convexly, the curvature being adapted to conform to the curvature maxillary sinus when the blade portion is implanted in the upper jaw of a living being.

39. An implant as claimed in any one of claims 35 to 38 wherein said blade portion has an arrowhead shape.

40. An implant as claimed in any one of claims 35 to 38 wherein said blade portion has a fishtail shape.

41. An implant as claimed in claim 16 comprising a support for a tooth crown, said support having a conically shaped portion comprising a porous surface portion and a crown mounting post extending axially from the larger diameter end of the conical portion.

42. A plastics endosseous implant adapted for tooth replacement in a living being, said implant comprising a surface portion having exposed interconnected pores adapted to promote only connective tissue ingrowth from surrounding sub-epidermal and osseous environments, said porous surface portion having preselected pore sizes restricted to the range of from 50 to 150 microns, and said interconnected pores in said surface portion extending to a

depth of at least two millimeters.

43. An implant as claimed in claim 42 wherein said plastic consists of essentially pure polymethylmethacrylate containing no polymerizing catalyst.

44. An implant as claimed in claim 42 or claim 43 wherein the porosity of said porous portion is in the range of 50 percent to 75 percent by volume.

45. An implant as claimed in claim 42 wherein said porous surface portion comprises part of a replica tooth root portion.

46. An implant as claimed in claim 45 comprising an elongate inner solid core portion in part of the root portion and a crown portion joined to said root portion.

47. An implant as claimed in claim 46 wherein said solid core portion has one end extending beyond said root portion and providing anchoring means for said crown portion.

48. An implant as claimed in claim 46 comprising at least one outwardly disposed shoulder portion along part of the length of the root portion adapted to implement the alveolar height in use, said shoulder portion having interconnected pores restricted to the range from 200 microns to 400 microns, the shoulder portion thereby being adapted to promote hard bony ingrowth from contiguous alveolar bone.

49. An implant as claimed in claim 42 or claim 43 comprising a support for a tooth crown, said support having a conically shaped portion comprising the porous surface portion of the implant and a crown mounting post extending axially from the larger diameter end of the conical portion.

50. An endosseous non-toxic polymer plastic implant comprising a porous surface portion adapted to mate with a corresponding bone implant site in a living being, said porous surface portion having pore sizes restricted to the range from 200 microns to 400 microns, a porosity restricted to the range from 50 percent to 75 percent, and a depth of at least two millimeters.

51. An endosseous plastic implant substantially as hereinbefore described with reference to and as illustrated in any one of the accompanying drawings.

52. A method of installing an endosseous implant as claimed in claim 16 or any of claims 42 to 51 in a bone of a living non-human animal comprising the steps of:

(a) forming a threaded hole in said bone and  
(b) screwing a mating threading implant portion into said hole, said implant portion having a porous surface with pore size in the range 200 - 400 microns from promoting hard bony ingrowth into said pores.

53. A method of installing an endosseous implant as claimed in claim 16 or any one of claims 42 to 51 in a bone of a living non-human animal comprising the steps of:

(a) forming a threaded hole in said bone and

(b) screwing a mating threaded implant portion into said hole, said implant portion having a porous surface with porous size in the range of 50 - 150 microns for promoting soft tissue ingrowth into said pores.

54. A method as claimed in claim 53 wherein the endosseous implant is a tooth crown support, and said bone is a jawbone.

55. A method as claimed in claim 54 wherein said threaded hole is formed by tapping threads in a natural alveolar socket.

56. A method as claimed in claim 55 comprising deepening said natural alveolar socket to compensate for inadequate alveolar height.

57. A method as claimed in claim 52 or claim 53 and substantially as hereinbefore described.

58. A method of implanting a replica tooth in an alveolar socket of a non-human animal where the adjacent bone height is abnormally low, the method comprising the steps of:

undercutting the dermis along each side of the bone ridge adjacent to the alveolar socket;

inserting a plastics replica tooth root portion into the alveolar socket, the tooth portion having a porous surface extending up to the normal line of gingival attachment, the porous surface having pore sizes in the range of 50 microns to 150 microns and the porosity extending to a depth of at least two millimeters;

building up the alveolar ridge to normal height by packing porous synthetic bone around the tooth root portion at the time of inserting the implant;

pulling the dermis and overlying gingiva up to the normal gum line of the tooth root portion; and

suturing the dermis and gingiva in place.

59. A method as claimed in claim 58 wherein the porous synthetic bone has pore sizes predominantly in the range of 200 microns to 400 microns.

60. A method of implanting a plurality of adjacent teeth in an alveolar environment of a non-human animal where the alveolar ridge is abnormally low, the method comprising the steps of

undercutting the dermis along the alveolar ridge at the location of a plurality of adjacent teeth to be implanted;

forming an artificial alveolar ridge of porous plastics to fit the natural bone at said location, said plastics ridge having pore sizes predominantly in the range from 200 microns to 400 microns, a porosity of from 50 to 75 percent and the surface of the ridge being porous to at least 2 mm;

installing crown mounting posts for the plurality of adjacent teeth in the top of the artificial alveolar ridge;

providing porous surfaces at the bases of the crown mounting posts to promote epithelial tissue attachment of the surrounding gingiva;

placing the artificial alveolar ridge in mating

- contact with the natural alveolar bone at said location;  
suturing the previously undercut gums in place around the bases of the crown mounting posts. 20
- 5 61. A method as claimed in claim 60 further comprising the step of attaching artificial tooth crowns onto said crown mounting posts after firm attachments have formed between the natural alveolar bone and the artificial ridge and between the gingiva and the bases of the crown mounting posts. 25
- 10 62. A method of correcting an abnormally low alveolar ridge adjacent to a natural tooth caused by periodontal disease in a non-human animal comprising the steps of:  
packing porous synthetic bone having pore sizes predominantly in the range from 200 microns to 400 microns, a porosity of from 50 to 75 percent and a depth of porosity of at least 2 mm around the natural tooth to build up the alveolus surrounding the tooth to normal height;  
pulling the dermis and gingiva up to the normal gum line of the tooth; and  
suturing the dermis and gingiva in place. 30
- 15 63. A method as claimed in claim 62 further comprising the preliminary step of:  
undercutting the dermis along each side of the bone ridge adjacent to the tooth. 35

ARTHUR ASHMAN

(BOULT, WADE & TENNANT)

27 Fumival Street, London, EC4A 1PQ 35  
Chartered Patent Agents

1576418

COMPLETE SPECIFICATION

12 SHEETS

This drawing is a reproduction of  
the Original on a reduced scale  
Sheet 1.

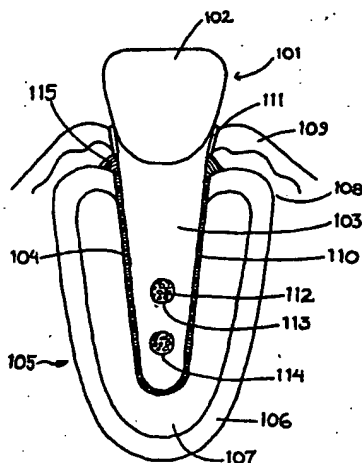


Fig. 1

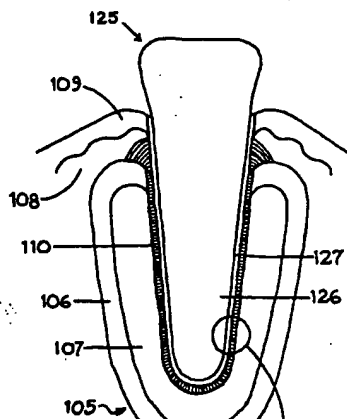


Fig. 5A

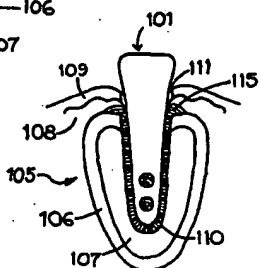


Fig. 2

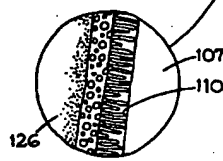


Fig. 5B

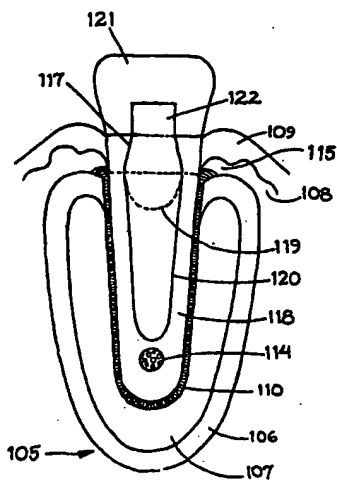


Fig. 3

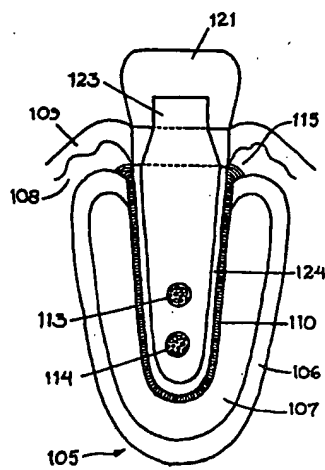


Fig. 4

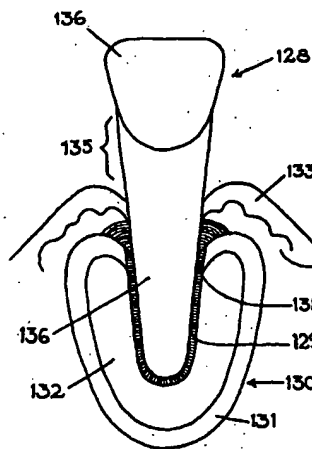


Fig. 6

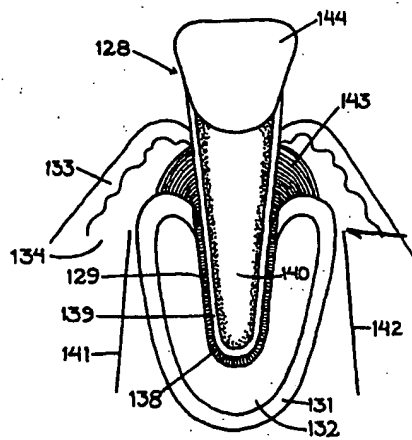


Fig. 7

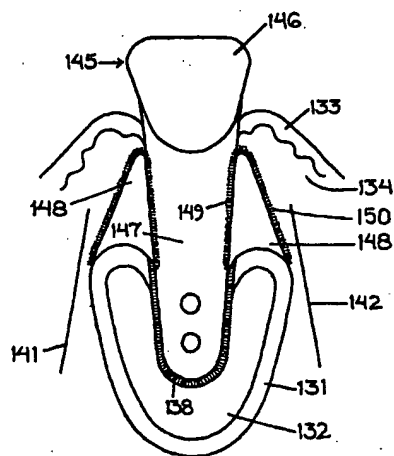


Fig. 8

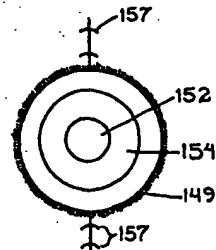


Fig. 9B

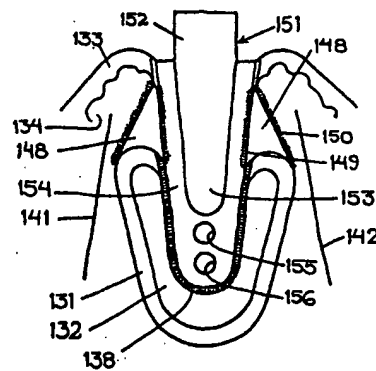


Fig. 9A

1576418

COMPLETE SPECIFICATION

12 SHEETS

*This drawing is a reproduction of  
the Original on a reduced scale  
Sheet 3*

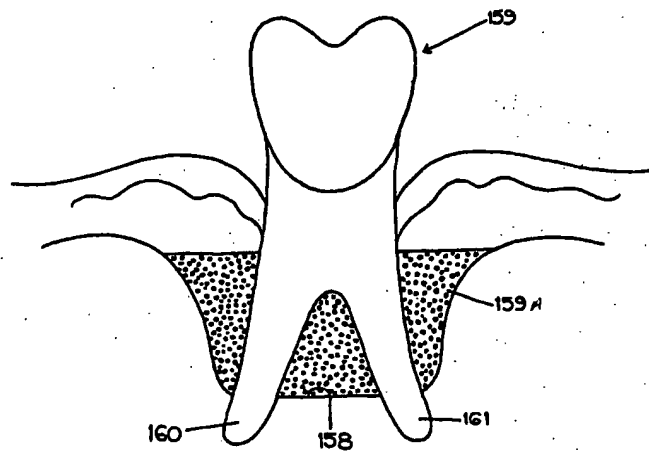
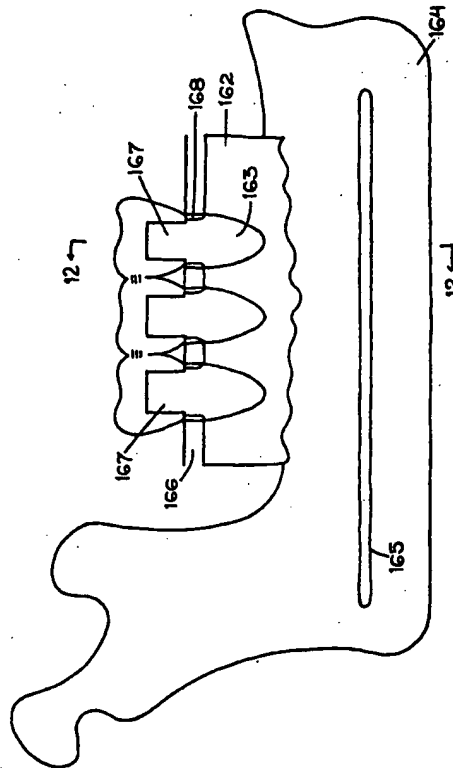
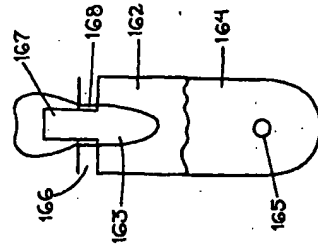
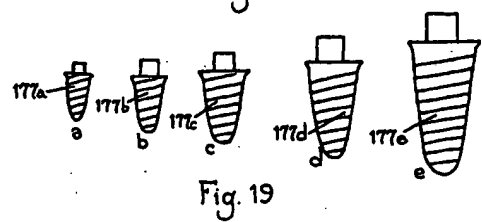
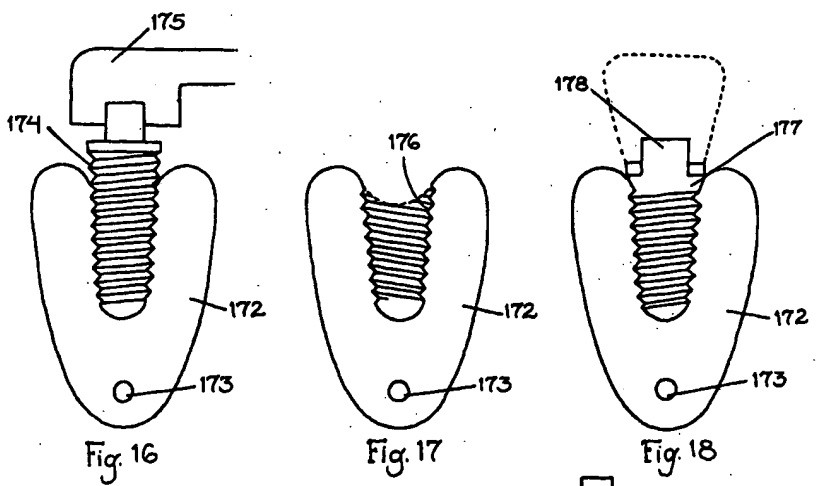
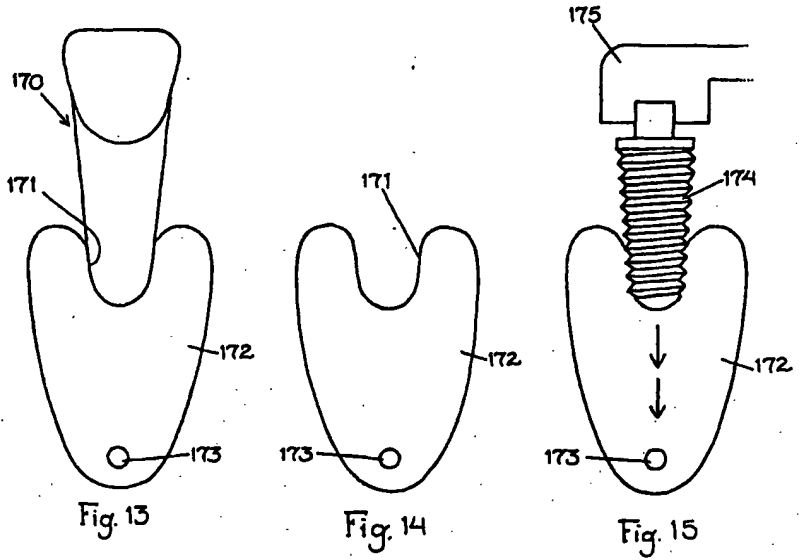


Fig. 10



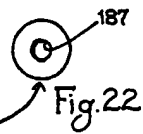
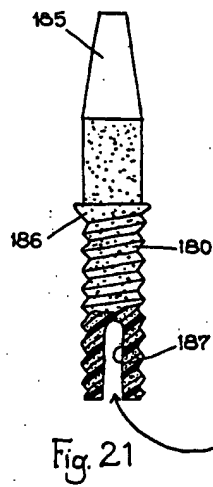
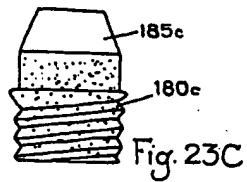
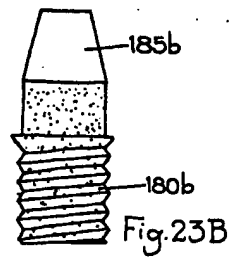
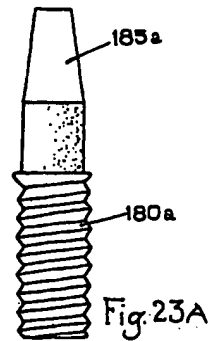
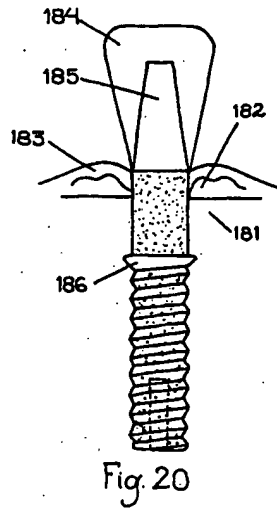


1576418

COMPLETE SPECIFICATION

12 SHEETS

This drawing is a reproduction of  
the Original on a reduced scale  
Sheet 6

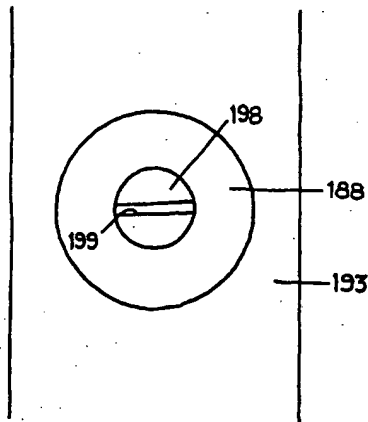
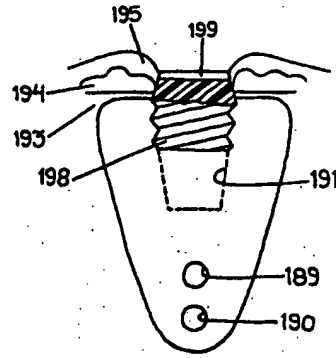
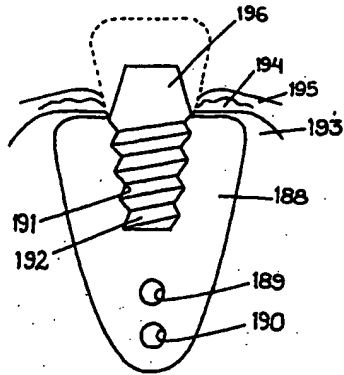


1576418

COMPLETE SPECIFICATION

12 SHEETS

*This drawing is a reproduction of  
the Original on a reduced scale  
Sheet 7*



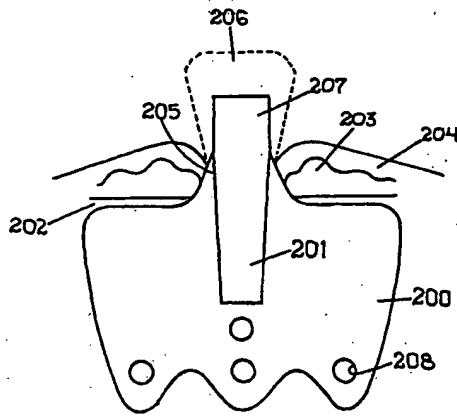


Fig. 27

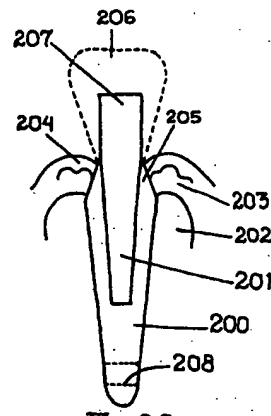


Fig. 28

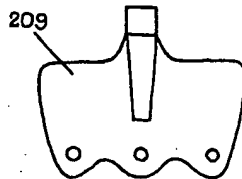


Fig. 30

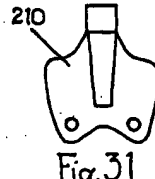


Fig. 31

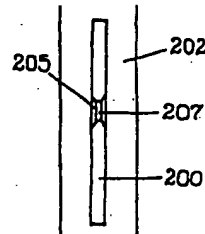


Fig. 29

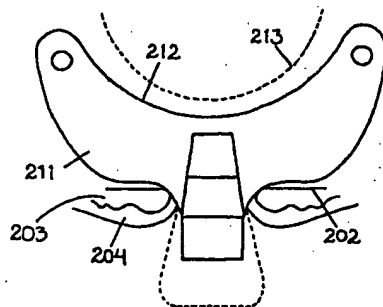


Fig. 32

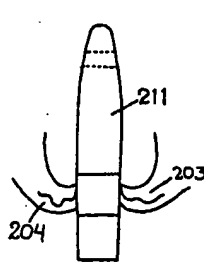


Fig. 33

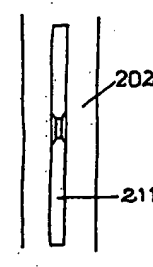


Fig. 34

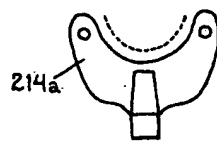


Fig. 35A

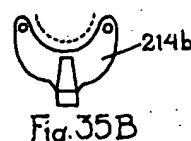


Fig. 35B

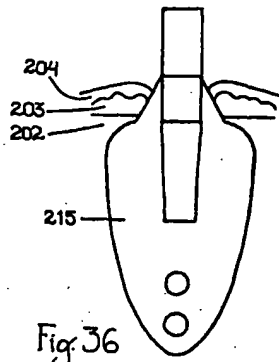


Fig. 36

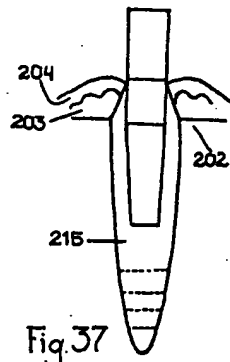


Fig. 37

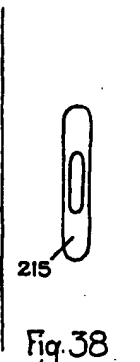


Fig. 38

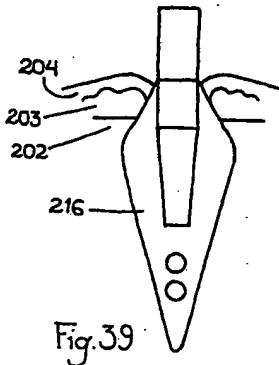


Fig. 39

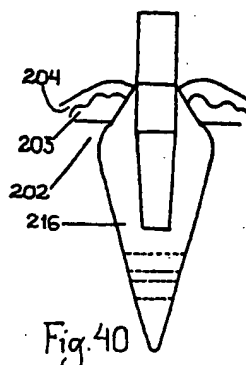


Fig. 40

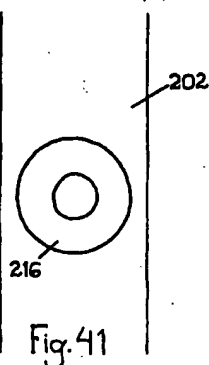


Fig. 41

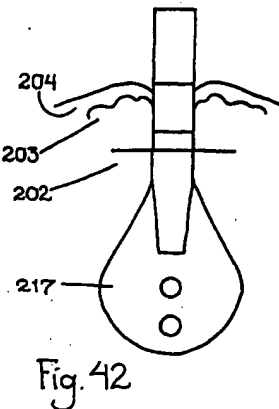


Fig. 42

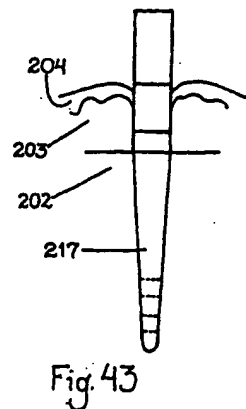


Fig. 43

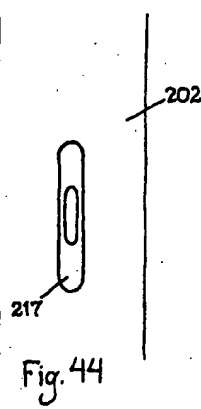
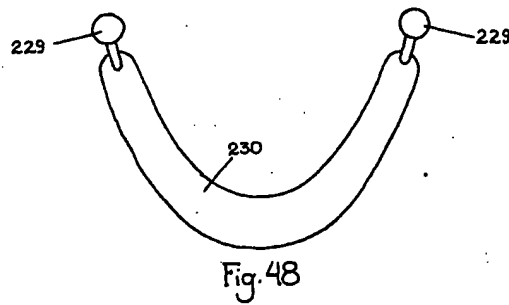
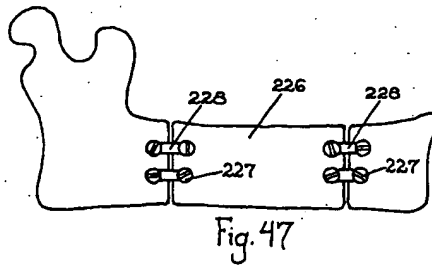
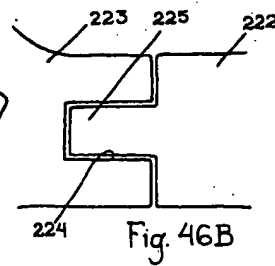
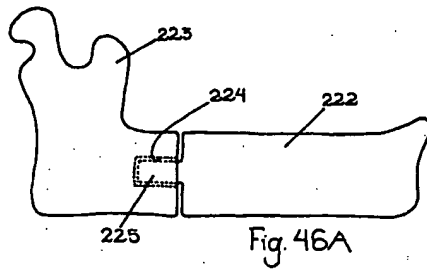
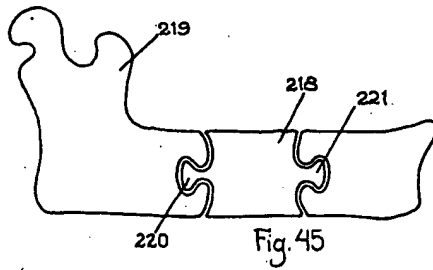


Fig. 44

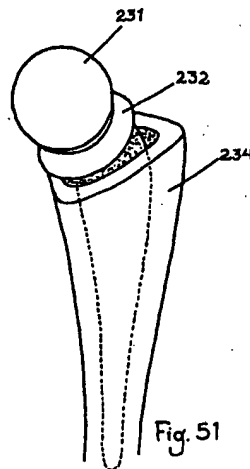
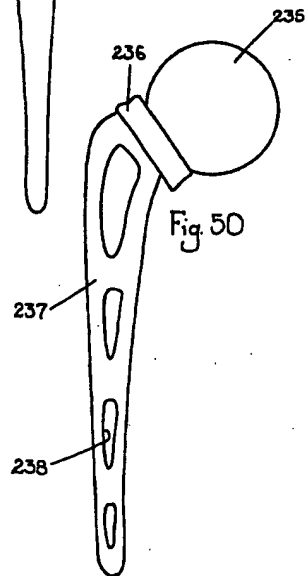
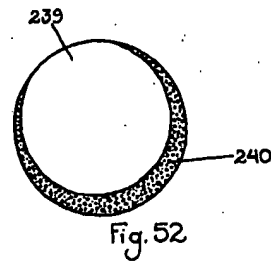
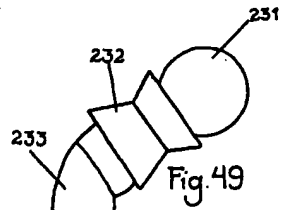


1576418

COMPLETE SPECIFICATION

12 SHEETS

*This drawing is a reproduction of  
the Original on a reduced scale  
Sheet 11*



1576418

COMPLETE SPECIFICATION

12 SHEETS

*This drawing is a reproduction of  
the Original on a reduced scale*  
Sheet 12

Fig 54

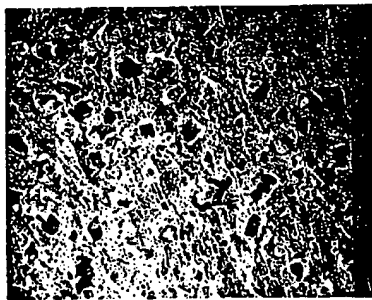


Fig. 53

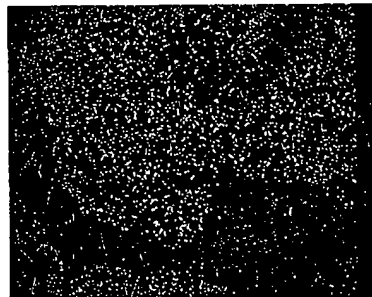


Fig. 55



**This Page is Inserted by IFW Indexing and Scanning  
Operations and is not part of the Official Record**

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☐ FADED TEXT OR DRAWING
- ☒ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☐ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: \_\_\_\_\_

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.**